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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/993,300	11/23/2001	George Jackowski	2132.107	5368
21917	7590	06/14/2005		
MCHALE & SLAVIN, P.A. 2855 PGA BLVD PALM BEACH GARDENS, FL 33410			EXAMINER COOK, LISA V	
			ART UNIT	PAPER NUMBER
			1641	

DATE MAILED: 06/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/993,300

Applicant(s)

JACKOWSKI ET AL.

Examiner

Lisa V. Cook

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 March 2005.
2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 39-46 is/are pending in the application.
4a) Of the above claim(s) 39-46 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☒ Claim(s) 1 and 39-46 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

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DETAILED ACTION

Amendment Entry

1. Applicants response to the Office Action mailed 07 December 2004 is acknowledged (Paper filed 3/31/05). In the amendment filed therein the specification and claim 1 were modified. Clams 2-38 were cancelled and new claims 39-46 were added. Currently claims 1 and 39-46 are pending. The new claims have prompted the following restriction requirement.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:
- I. Claims 1 is drawn to an isolated biopolymer selected from SEQ ID NO: 1 or SEQ ID NO:2, classified in class 530, subclass 300 or class 530, subclass 350 for example.
 - II. Claims 39-43 are drawn to methods which not only detect SEQ ID NO: 1 or SEQ ID NO:2, further requiring a correlation to disease state, diagnosing, therapeutic avenues, an/or risk assessment, classified in class 436, subclass 518 and class 424, subclass 93.1 for example.
 - III. Claims 44-46 are drawn to a kit containing SEQ ID NO: 1 or SEQ ID NO:2 and antibodies that bind said sequences, classified in class 422, subclass 61 for example.
3. The inventions are distinct, each from the other because of the following reasons:

A. The method/kit inventions of Group **II** and **III** are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the inventive methods/kits are patentably distinct. Group II *merely detects* Seq Id No: 1 or Seq Id No: 2, while Group III is drawn to methods/kits that *include* Seq Id No: 1 or 2 and further correlates the detection to disease state assessment, product regulation, and therapeutic evaluations. The addition of the biopolymers or the additional correlation is not required in the kit of invention II. Therefore the methods/kits utilize different reagents and have different method steps (different modes of operation/function/effects).

B. Inventions (**I**) and (**II and III**) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product (invention I) can be used in any of the materially different processes/kits of invention II and III.

It is recognized that although the search for the inventions may overlap they are not totally co-extensive, where the search for one would fully encompass the search for the others. Because these inventions are distinct for the reasons given above and the search required for Inventions I-IV are not mutually inclusive (i.e. the search for one invention is not required for the other inventions) restriction for examination purposes as indicated is proper.

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Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. Please note that the classifications in the restriction are illustrative only and **do not** represent all the classes and subclasses which must be searched for each invention; nor is the search limited to issued US patents, but rather includes foreign patents and applications as well as literature searches.

5. Newly submitted claims 39-46 are directed to an invention that is independent or distinct from the invention originally claimed for the reasons presented above. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 39-46 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

6. Currently claim 1 is under consideration.

7. Rejections and/or objections of record not reiterated below have been withdrawn

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OBJECTIONS WITHDRAWN

Information Disclosure Statement

8. Applicants contend that references cited in the specification but not included on information disclosure statement provided only general back information and the state of the art. This information was not deemed pertinent to the patentability of the claimed invention. This argument have been considered and was found persuasive. Accordingly, the objection is withdrawn.

Specification

9. Applicant has corrected the noted deficiencies in the specification. Thus the objection to the specification is withdrawn.

Abstract

10. Legal terminology has been eliminated from the abstract, therein obviating the objection. The objection is withdrawn.

REJECTIONS WITHDRAWN

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

11. Claim 1 has been modified so as not to be directed to non-statutory subject matter. The rejection is withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

12. Claim 1 no longer read on the use of the biopolymer markers for Alzheimer's disease. In fact claim 1 does not set forth any utility. The prior art exhibits structures comprising the sequences set forth and therefore meet the utility requirement for sequences comprising SEQ ID NO:1 and comprising SEQ ID NO:2. The rejection is withdrawn.

NEW GROUNDS OF REJECTION NECESSITATED BY AMENDMENT

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

13. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claim 1 does not include a proper transition phrase "comprising" or "consisting of" in the claim. Accordingly it is not clear as to what the sequence will encompass. As recited the metes and bounds of the claims cannot be determined and one of ordinary skill in the art would not be appraised of the scope of the instant invention.

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The claim is in the proper Markush Format reciting –selected from the group consisting of. However this language provides closed interpretation between SEQ ID NO:1 and SEQ ID NO:2, it does not clearly identify Applicants intended scope for SEQ ID NO:1 and SEQ ID NO:2. It is suggested that the appropriate transition phrase be added to the claim in order to obviate this rejection. For example, An isolated biopolymer marker selected from the group consisting of sequences comprising SEQ ID NO:1 and comprising SEQ ID NO:2. Appropriate correction is required.

REJECTIONS MAINTAINED

Claim Rejections - 35 USC § 102

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

I. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Wilson (Science, 282:2012-2018, 1998).

Wilson discloses sequences comprising or having SEQ ID NO:2. See GenCore protein search dated 8/3/04. Although the reference is silent with respect to the marker indicating a particular disease state like Alzheimer's disease, this is deemed inherent to the biopolymer.

A structure which necessarily functions in accordance with the limitations of a process or method claim anticipates the claim. *In re King* (CCPA 1986) 231 USPQ 136.

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In other word the sequences set forth in claim 1 would inherently be markers for the claimed diseases. A compound and its properties are inseparable. *In re Papesch*, 315 F.2d 381, 137 USPQ 43 (CCPA 1963). Applicants sequence identification number 2 is disclosed as sequence identification number 5 (Q9N3X8) in the reference to Wilson. Therein the claimed sequence is taught.

II. Claim 1 is rejected under 35 U.S.C. 102(a) as being anticipated by Finan et al. (PNAS, 98, 9889-9894, 2001).

Finan et al. discloses sequences comprising or having SEQ ID NO:1. See GenCore protein search dated 8/3/04. Although the reference is silent with respect to the marker indicating a particular disease state like Alzheimer's disease, this is deemed inherent to the biopolymer. A structure which necessarily functions in accordance with the limitations of a process or method claim anticipates the claim. *In re King* (CCPA 1986) 231 USPQ 136. In other word the sequences set forth in claim 1 would inherently be markers for the claimed diseases. A compound and its properties are inseparable. *In re Papesch*, 315 F.2d 381, 137 USPQ 43 (CCPA 1963). Applicants sequence identification number 1 is disclosed as sequence identification number 2 (C95985) in the reference to Finan et al. Therein the claimed sequence is taught.

III. Claim 1 is rejected under 35 U.S.C. 102(a) as being anticipated by Galibert et al. (Science, 293, 668-672, 2001).

Galibert et al. discloses sequences comprising or having SEQ ID NO:1. See GenCore protein search dated 8/3/04.

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Although the reference is silent with respect to the marker indicating a particular disease state like Alzheimer's disease, this is deemed inherent to the biopolymer. A structure which necessarily functions in accordance with the limitations of a process or method claim anticipates the claim. *In re King* (CCPA 1986) 231 USPQ 136. In other word the sequences set forth in claim 1 would inherently be markers for the claimed diseases. A compound and its properties are inseparable. *In re Papesch*, 315 F.2d 381, 137 USPQ 43 (CCPA 1963).

Applicants sequence identification number 1 is disclosed as sequence identification number 2 (C95985) in the reference to Galibert et al. Therein the claimed sequence is taught.

Response to Arguments

Applicants contend that the copy of the search report and corresponding references cited under 35 USC 102 were received. Examiner apologizes for this mailing error and have attached the appropriate copies with the instant communication.

Furthermore, Applicant argues that the cited references under 102 are drawn to large sequence structures that include the claimed sequence identification numbers but do not anticipate sequences consisting of SEQ ID NO:1 and consisting of SEQ ID NO:2. This argument has been carefully considered but was not found persuasive because the claims do not read on sequences consisting of SEQ ID NO:1 and SEQ ID NO:2. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., sequences consisting of SEQ ID NO:1 and sequences consisting of SEQ ID NO:2) are not recited in the rejected claim(s).

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Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Accordingly, the rejections are maintained.

18. For reasons aforementioned, no claims are allowed.

19. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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20. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Group 1641 – Central Fax number is (571) 273-8300, which is able to receive transmissions 24 hours/day, 7 days/week. In the event Applicant would like to fax an unofficial communication, the Examiner should be contacted for the appropriate Right Fax number.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa V. Cook whose telephone number is (571) 272-0816. The examiner can normally be reached on Monday - Friday from 7:00 AM - 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (571) 272-0823.

Any inquiry of a general nature or relating to the status of this application should be directed to Group TC 1600 whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

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Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free).



Lisa V. Cook
Remsen 3C-59
(571) 272-0816
6/10/05



LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

06/10/05